

Plant Systems Audit Checklist and Scoresheet



Date of Audit: 01/01/2004

Facility Name: Sample Form

Plant Address:

City:

State:

Zip:

Country: USA

Telephone:

Fax:

FDA Food Facility Registration No.

Yes

Verified affidavit

Mailing Address:

Address:

Same as Above

City:

State:

Zip:

Contact Person for USDA:

Name:

Title:

Evaluation Elements	Facility Score	Percentage of Available Points Score	Minimum Points Required	Possible Points
I. Food Safety	300	100%	270	300
II. Quality Management Systems	80	100%	64	80
III. Personnel	125	100%	100	125
IV. GMPs/Sanitation	275	100%	220	275
V. Pest Control	50	100%	40	50
VI. Packaging/Labeling/Warehousing	100	100%	80	100
VII. Recall/Return	70	100%	56	70
VIII. Food Security	80	100%	64	80

Scoring System	Audit Results Summary
Possible Points 98.5% to 100% = Superior 95.0% to 98.4% = Excellent 87.5% to 94.9% = Acceptable Less than 87.5% = Unacceptable	Facility Score (total points): 1080 Facility Score (percent): 100.0% Facility Rating : Superior
If Unacceptable, account:	

Auditor:

Auditor's Signature: _____

Version 01012004

U.S. Department of Agriculture, AMS, F&V, PPB
STOP 0247, 1400 Independence Ave., SW, Washington, DC 20250
Ph: (202)-720-5021 / Fax: (202)-690-1087

Supplier: Sample Form, ,
Audit Date: 01/01/2004

Products packed:

Summary of Deficiencies:

Observations/Comments:

I. Food Safety

A. Internal Quality Audit

1.*	0	Are there procedures in place for management/supervisors to conduct internal reviews of Quality Systems?
2.	0	Are Internal audit findings documented and reported to upper management?
3.*	0	Are Corrective Action Reports followed up and documented to determine effectiveness?

B. Purchasing

4.	0	Is there a system in place to evaluate and approve suppliers?
5.	0	Are suppliers evaluated for good agricultural practices? (i.e. Do they have process controls in place covering pesticide control, harvesting, and transportation practices?)
6.	0	Are purchasing documentation/records, including Certificates of Conformance (COC) and Certificates of Analysis (COA), maintained, current, and applicable?
7.*	0	Are receipt inspections performed and documented on incoming product (Product condition, accuracy of invoice, product identity, etc.)? Is there documentation of the disposition of rejected product?
8.*	0	Are acceptance criteria documented for incoming ingredients? Do these procedures include testing for quality, foreign material, pesticides, and/or microbial contamination?
9.	0	Is domestic origin compliance verified? (i.e., product can be traced to US origins) (where required by contract)

C. Process Control (see attached for appropriate commodity)

10.	0	Is there a system in place for the proper handling, segregation, and storage of raw materials?
11.	0	Are raw materials washed or cleaned as necessary to remove soil or other contamination?
12.*	0	If water is part of the finished product, is there a drinking water quality analysis available? (chemical analysis)?
13.*	0	Is the processing/ingredient water potability certificate available? Date of certificate:
14.*	0	Is forced air that is used on product or food contact surfaces free from contaminations?
15.1/	0	Microbiological testing includes: 0 Tests required by specification or contract: 0 Routine analysis of food contact surfaces: 0 Environmental testing program (floors, walls, ceilings, etc.): 0 Testing of finished product:
16.	0	Is there a documented empty package integrity testing program? (e.g., can, mylar

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

		bags, paper sacks, etc.)
17.*	0	Are procedures in place to prevent shipment/use of non-conforming raw materials or finished product?
18.	0	Are ingredients properly weighed out and pre-blended according to the formula or specification?
19.*	0	Are sensitive ingredients maintained at the correct temperature during staging?
20.	0	Is product handled in manner designed to preclude contamination?
21.	0	Are in-process thermometers, timers, etc. properly calibrated according to a defined schedule and are results documented?

D. Foreign Material Contamination Prevention (Complete 1. and/or 2., as appropriate)

1. Metal Detection

22.*	0	Is calibration performed with ferrous, non-ferrous, and stainless steel standards? Verification?
23.*	0	Is there adequate documentation of metal detector's operation?
24.*	0	Is there an automatic rejection system in place and is it functioning properly?
25.*	0	Is there a written action plan in place for when test or metal detector fails?

2. In-line Magnet Traps, In-line Screen, Line filters, Blower or Rock Traps

26.*	0	Are there an adequate number/location of magnets/screens/filters? Is the frequency of inspection of the magnets/screens/filters adequate? Are the results of every magnet/screen/filter inspection documented?
27.*	0	Does a written action plan exist for when integrity of magnets/screens/filters has been compromised?

3. Extraneous Physical Hazard Prevention Program

28.*	0	Are light bulbs protected?
29.*	0	Is there a glass container accounting system in place?
30.*	0	Are can cleaners (steam, air or water) located on each line for glass, tin or semirigid containers?
31.	0	Is facility free from peeling paint, rust, loose nuts and bolts?

E. Allergen Controls

32.	0	Are there procedures in place for management to identify all allergenic materials present in the facility? What are the allergens that have been identified?
33.	0	Are raw material supplies organized in such a way to prevent cross-contamination of products? Are these procedures applied to product being processed and to stored finished product? (Physical segregation/labeling)
34.	0	Are production schedules planned to eliminate possible cross-contamination?
35.	0	Do sanitation procedures address the issue of possible cross-contamination between products? (All allergens cleaned from processing surfaces, etc.)
36.	0	Is allergen control a part of the company's training program with all employees?

37.	0	Is the presence of an allergen clearly stated on finished product labels in terms understandable by the consumer? Does the firm include warning statements (for example, "May contain peanuts" or "Produced in a facility where peanuts are processed") on product labels when appropriate?
38.	0	Does the company's internal audit system include a review of their allergen control procedures?

II. Quality Management Systems

A. Documentation/Control of Records

39.	0	Are quality systems records kept for required amount of time (minimum of three years)?
40.	0	Are procedures implemented to handle review of records?
41.	0	Are records legible, readily retrievable and protected from deterioration?
42.	0	Do company forms include revision date and form number?

B. Quality Assurance/Control Department

43.*	0	Is the Quality Assurance Department adequately staffed to perform product evaluations?
44.	0	Are finished product inspections performed and documented to ensure that the product conforms to specifications?
45.*	0	Are in-process quality checks performed throughout production?
46.	0	Are laboratory facilities sufficient to perform necessary analysis?
47.*	0	Are all records of product evaluations and analysis complete?
48.	0	Are product evaluation records kept throughout the shelf life of the product plus two years? (or three years, whichever is greater)
49.	0	Are reagents labeled and stored according to manufacturer's requirements and recommendations?
50.	0	Is there complete documentation of calibration on equipment? (schedule, procedures and results?)
51.	0	Is calibration certification of scales performed by a licensed agency? (minimum of annually)

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

III. Personnel

52.*	<input type="checkbox"/>	Do employees wear clean outer garments, gloves, and aprons that are readily washable as appropriate?
53.*	<input type="checkbox"/>	Do employees wear effective hair and beard restraints?
54.*	<input type="checkbox"/>	Are employees free from loose jewelry?
55.*	<input type="checkbox"/>	Are employees working in direct contact with food free from infected lesions or skin diseases?
56.*	<input type="checkbox"/>	Do employees wash and sanitize hands when entering the processing area? (as applicable)
57.*	<input type="checkbox"/>	Do employees remove protective outer garments prior to leaving the processing area where necessary? (e.g., aprons, lab coats, gloves, etc.)
58.*	<input type="checkbox"/>	Are personal item storage and food consumption in a separate area away from production?
59.1/	<input type="checkbox"/>	<p>Is there regularly scheduled training for new and continuing employees in the following areas?</p> <p><input type="checkbox"/> Hygiene Sanitation:</p> <p><input type="checkbox"/> Good Manufacturing Practices:</p> <p><input type="checkbox"/> Food Safety:</p> <p><input type="checkbox"/> Employee Safety:</p> <p><input type="checkbox"/> Job/Task Performance:</p> <p><input type="checkbox"/> Company Quality Policy and Practices:</p>
60.	<input type="checkbox"/>	Are records kept of all training?
61.	<input type="checkbox"/>	Are signs posted indicating hazardous areas and where protective gear is required?
62.	<input type="checkbox"/>	Is there a Lock out/Tag out program for equipment (including training, instruction, and program implementation)?
63.	<input type="checkbox"/>	Is appropriate safety equipment worn by employees (as designated by the company)?
64.	<input type="checkbox"/>	Are material safety data sheets (MSDS) readily available and properly maintained?

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

IV. Good Manufacturing Practices

A. Facilities, Equipment and Outside Premises

65.	0	Are the outside premises properly surfaced to prevent dust and offensive odors and to promote drainage?
66.	0	Are the outside areas maintained in a manner which will prevent rodent and insect harborage?
67.	0	Are floors, doors, ceilings, walls and overheads in good repair and designed to facilitate proper sanitation and maintenance?
68.	0	Are there back flow prevention devices installed on all water and steam lines?
69.1/	0	Condition (Including proper temperatures) of: 0 Ingredient and raw material storage: 0 Cooler/Freezer: 0 Preparation areas: 0 Processing area: 0 Filling area: 0 Finished Product Storage:
70.	0	Is there a locked storage area for chemicals, cleaning compounds and similar materials separate from product ingredients and container storage? Are chemicals clearly and properly labeled?
71.	0	Is there sufficient lighting to permit efficient operations and cleaning?
72.	0	Are buildings reasonably free from excessive dust, heat, steam, condensation, vapors, smoke or fumes?
73.*	0	Are product contact surfaces of equipment, containers and utensils made of nonabsorbent corrosion resistant material?
74.	0	Is product contact equipment cleanable and in good repair?
75.*	0	Are containers and utensils used in handling the product cleaned, stored and utilized in such a manner as to preclude an unsanitary condition?
76.*	0	Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?
77.*	0	Are catwalks and stiles constructed and located to prevent product contamination?
78.	0	Is equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?
79.*	0	Are production and preparation areas enclosed?
80.*	0	Are doors, windows and other gateways properly protected with screens, air screens or other protective devices?
81.	0	Is there a documented maintenance schedule for equipment and facilities?

B. Plant Sanitation

82.*	0	Is there a formal documented sanitation program?
83.	0	Name and Title of authorized personnel responsible for sanitation and

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

		pre-inspections:
84.	0	Is all major equipment disassembled for cleaning or can be cleaned-in-place (CIP)?
85.	0	Are all areas maintained in a clean orderly manner?
86.	0	Does the documented sanitation program include a master cleaning schedule for all production areas, equipment and facilities? Is it available and implemented?
87.*	0	Is sanitation of equipment maintained throughout the day to prevent product contamination?
88.	0	Are routine pre-operation sanitation inspections conducted and documented? Are follow-up procedures documented?
89.1/	0	Rest room facilities: 0 Are they clean, dry and of good general appearance? 0 Do they open directly into production area? 0 Do they have hot and cold water? 0 Do they have sanitizing or antimicrobial soap? 0 Do they have signs posted indicating the importance of hand washing (multilingual if appropriate)? 0 Do they have independent outside ventilation? 0 Do they have clean and accessible waste receptacles? 0 Are the restrooms equipped with self-closing doors? 0 Are they well lighted?
90.	0	Is the capacity of the waste storage sufficient?
91.	0	Is there timely removal of waste?
92.	0	Is idle equipment stored in an orderly fashion?
93.1/	0	Do the hand wash and/or hand dip stations have: 0 Posted signs (bilingual/multilingual)? 0 Sanitizing or antimicrobial soap (Type)? 0 Waste receptacles? 0 Cold and hot water? 0 Controls other than hand operated? 0 Appropriate locations? 0 Acceptable conditions?

GMP Violations: List all violations not previously identified in the report and deduct 5 points for each:

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

V. Pest Control

94.*	0	Is facility free from pest infestation? (insect, bird, rodent, etc.)?
95.	0	Is pest control station map properly maintained and available?
96.	0	Are pest control devices properly installed and monitored?
97.*	0	Is routine maintenance and inspection of pest control devices documented?
98.	0	Are the number and placement of pest control/deterrent devices adequate to prevent infestation?
99.	0	Are pest control records maintained for at least three years?
100.	0	Are all pest control chemicals properly identified and separated from potentially hazardous cross-contamination?
101.	0	Is the application of restricted use pesticides conducted or supervised by a licensed pest control operator?

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

VI. Packaging/Labeling/Warehousing

102.*	0	Are packaging materials clean and stored in dry, clean location?
103.	0	Are visual examinations of packaging completed and documented after closure? (This includes sealing, labeling and coding)
104.	0	Are the packages coded and labeled correctly and legibly? (e.g., does what is in package match the label?)
105.1/	0	Package fill/net weights: 0 Have guidelines been established and is a procedure in place to verify compliance? 0 Are corrective actions taken as needed documented?
106.	0	Are miscoded or mislabeled packages documented and discarded or corrected as appropriate?
107.*	0	Are empty containers protected from contamination?
108.	0	Are there sufficient facilities for handling raw materials and appropriate rotation of materials (first-in, first-out)?
109.*	0	Does raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects?
110.*	0	Are there temperature-recording devices or a high temperature alarm located in the refrigeration or freezer facilities?
111.	0	Is there a shelf-life sample retention program in place?
112.*	0	Is there appropriate rotation of finished products (first-in, first-out)?
113.	0	Is finished product stored in designated area and separated from raw ingredients?
114.*	0	Is trailer/railcar cleaning and inspection performed and documented prior to loading?

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

VII. Recall/Return Program

115.	0	Is retained product identified and stored in a clearly designated area?
116.*	0	Is a log of Hold product maintained? Are records kept documenting the disposition of Hold product?
117.	0	Is there a person authorized to release product? (Name/Title)
118.*	0	Is there a recall procedure written and tested according to a defined schedule not less than annually?
119.	0	Are returned goods received in a clearly designated area?
120.*	0	Are raw ingredients traceable throughout the process?
121.	0	Is reworked product documented and traceable?
122.*	0	Is there product tracking capability to the customer?
123.	0	Does product tracking system include container code?
124.	0	Is there a system in place and documented to handle customer complaints?

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

VIII. Food Security

125.*	0	<u>Management</u> - A Food Security Plan is established, implemented, and reassessed by management to assure it remains relevant to the operation.
126.*	0	<u>Management</u> - The Food Security Plan addresses preventative measures relative to product tampering and deliberate contamination at the processing facility and during transport in commerce.
127.	0	<u>Management</u> - Written security practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue.
128.*	0	<u>Human Element - Staff</u> - Company personnel hiring practices include screening all potential employees. Photo identification or other measures are employed to restrict access to the facility.
129.*	0	<u>Human Element - Staff</u> - Facility employees have received training in Food Security. The Food Security training is documented.
130.*	0	<u>Human Element - Public</u> - Supplier delivery personnel, contract workers, and visitors are restricted access to vulnerable product areas of the processing and storage facility when not accompanied by a company representative.
131.*	0	<u>Facility</u> - The outside premises are secure with limited access to vulnerable areas. The grounds and facility are monitored for suspicious activity and unauthorized entry. "No Trespassing" signs are visible along the perimeter of the facility, or other measures are being taken to secure and limit access to vulnerable areas.
132.*	0	<u>Operations</u> - Assurances are provided by suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials concerning security practices. This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.
133.	0	<u>Operations</u> - The security of water and utilities within the company's control are addressed in the company's plan and define limited access by designated company representatives.

* 10 point question. 1/ each section of the question is worth 5 points. All other questions are worth 5 points each.
NOTE: Contract Review--no points assigned.

IX. Contract Review: (Complete only if plant packs for Government Contracts)

No points assigned. Answer Yes or No with explanation	
134.	Are procedures documented and implemented to ensure contract terms can and will be met?
135.	Are defined procedures documented and implemented for handling amendments?
136.	Are records of contract reviews and amendments kept?